PART 153—REGISTRATION POLICIES AND INTERPRETATIONS

Subparts A—C [Reserved]

Subpart D—Reporting Requirements for Risk Benefit Information

Subparts E—F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

Subpart H—Coloration and Discoloration of Pesticides

Subparts I—L [Reserved]

Subpart M—Devices

AUTHORITY: 7 U.S.C. 136w.

Subparts A—C [Reserved]

Subpart D—Reporting Requirements for Risk Benefit Information

SOURCE: 50 FR 38121, Sept. 20, 1985, unless otherwise noted.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, subpart D was removed and reserved, effective August 18, 1995.

§ 153.61 What the law requires.

Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states: ''If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.''

§ 153.62 Definitions.

(a) The definitions set forth in FIFRA sections 2 and in part 152 of this chapter apply to this part.

(b) The term *registrant* includes any person who holds a registration for a pesticide product issued under FIFRA section 3 or 24(c).

[50 FR 38121, Sept. 20, 1985; 50 FR 42020, Oct. 17, 1985, as amended at 53 FR 15998, May 4, 1988]

§ 153.63 Who must submit information.

FIFRA section 6(a)(2) imposes a reporting duty on the ''registrant.'' However, FIFRA section 14(b)(4) states: ''When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.'' Thus an act or omission (such as a failure to report information) of any employee or agent of a registrant, or of any person acting for a registrant, is to be regarded as the act or omission of the registrant.

§ 153.64 When information must be submitted.

(a) Information which is otherwise reported under this part must be submitted to EPA when the registrant first comes into possession of or knows of such information. However, except as provided under § 153.70(a)(1) and (2), EPA will consider such information to be submitted on time if it is received by EPA not later than the 15th working day after the registrant first possesses or knows of the apparently reportable information. Submission of such information after the 15th working day will be considered to be an actionable violation of FIFRA section 6(a)(2).

(b) A registrant possesses or knows of information at the time any officer, employee, agent, or other person acting for or employed by the registrant and capable of appreciating the significance of such information first comes into possession of or knows of such information. This includes information which a prudent person similarly situated

could reasonably be expected to possess or have knowledge of.

(c) In monitoring a registrant's compliance with the prescribed reporting periods, EPA will determine whether the registrant has established and followed procedures for expeditiously processing pertinent information, and will take this into account when making enforcement decisions. Registrants must recognize and accept responsibility for becoming cognizant of pertinent information which their officers, employees or agents possess or know of, and for ensuring that such information is submitted to EPA within the prescribed reporting periods.

§ 153.65 How information should be submitted.

A submission should:

(a) Be sent by certified mail, or in any other way permitting verification of its receipt by the Agency;

(b) Be addressed to: Registration Division (TS–767C), U.S. Environmental Protection Agency, Washington DC 20460;

(c) Contain the name of the submitter, the company name and number, the date of transmittal to EPA, and a statement that the information is being submitted in accordance with FIFRA section 6(a)(2);

(d) Identify the substance tested or otherwise covered by the information (including, if known, the CAS Registry Number);

(e) Comply, to the extent applicable, with any requirements issued by the Agency under FIFRA section 3(c)(2)(B) and/or section 3(c)(1)(D) for the flagging of data demonstrating possible adverse effects;

(f) Summarize the information being submitted;

(g) Assert any claims of confidentiality for information contained in the submission;

(h) If submitted under another provision of FIFRA (e.g., section 3(c)(2)(B)), comply with all applicable requirements for the submission of data under such provision.

§ 153.66 What information must be submitted.

This section sets forth EPA's interpretation of the requirements of FIFRA section 6(a)(2). Note also that §§ 153.69 through 153.78 of this part set forth EPA's enforcement policy regarding which failures to submit information EPA will regard as actionable violations of FIFRA section 6(a)(2).

(a) *Requirement.* EPA interprets FIFRA section 6(a)(2) to require a registrant to submit information to EPA if:

(1) The registrant ''has'' the information, i.e., the registrant (or any officer, employee, agent, or other person acting for or employed by the registrant) possesses or knows of the information;

(2) The information pertains to a pesticide for which that registrant holds a registration under FIFRA;

(3) The information, if true, would be relevant, either by itself or in conjunction with other information, to an Agency decision regarding the risks and benefits of the pesticide, i.e., an Agency decision regarding the registerability of the pesticide or regarding the proper terms and conditions of the registration of the pesticide; and

(4) The exclusions in paragraph (b) of this section do not apply to the information.

(b) *Exceptions.* Notwithstanding paragraphs (a)(1), (2) and (3) of this section, EPA does not interpret FIFRA section 6(a)(2) to require the submission to the Agency of information:

(1) *Non-expert opinion.* If it consists solely of opinion(s) or conclusion(s), unless expressed by a person:

(i) Who was employed or retained (directly or indirectly) by the registrant to express an opinion or conclusion which relates in any way to the pesticide's properties, effects, risks, or benefits; or

(ii) From whom the registrant requested the opinion(s) or conclusion(s) in question; or

(iii) Who by virtue of his knowledge, skill, experience, training, or education would be permitted to testify to the opinion(s) or conclusion(s) in a court under Rule 702 of the Federal Rules of Evidence; or

(2) *Previously submitted information.* If it has previously been submitted to the Agency.

(i) *Information considered to have been previously submitted.* Information shall be considered to have been previously submitted to EPA for purposes of this part if such information is contained completely in:

(A) Documents previously submitted to EPA by the registrant;

(B) Any scientific article or publication which has been abstracted in Biological Abstracts, Chemical Abstracts, Index Medicus, or Pesticides Abstracts, if the abstract in question clearly identified the active ingredient or the registered pesticide(s) to which the information pertains (information received by or known to the registrant prior to publication of an abstract concerning the information must be reported and may not be withheld pending such publication);

(C) EPA publications, EPA hearing records, or publications cited in EPA FEDERAL REGISTER notices.

(D) Reports or publications which have been made available to the public by any of the following Federal agencies: Center for Disease Control, Consumer Products Safety Commission, Department of Agriculture, Department of the Interior,

Food and Drug Administration, National Institutes of Health, or Occupational Safety and Health Administration (otherwise reportable information concerning research which was performed, sponsored, or funded by the registrant which may also appear in a forthcoming Government report or publication must be reported and may not be withheld pending publication); or

(E) Any other documents which are contained in the official files and records of the EPA Office of Pesticide Programs.

(ii) *Discussion.* Section 6(a)(2) applies only to ''additional'' information. Thus, if a registrant has previously submitted information concerning a given study, document, or incident, the same information need not be submitted again. In addition, EPA does not believe that it would serve any useful purpose to insist that registrants submit information which is already in EPA files or is otherwise readily accessible to EPA. Accordingly, EPA has specified a number of objectively defined categories of information which need not be submitted. Failure to submit information in any of these categories will not be treated as an actionable violation of section 6(a)(2). While the specified categories are not intended to encompass all information which could conceivably come to the attention of Agency personnel, they do indicate which types of information are most likely to be routinely examined or reviewed by EPA.

§ 153.67 What are the consequences of a failure to submit required information.

(a) Failure to submit, on time, information of the type described in §§ 153.69 through 153.78 and otherwise reportable under § 153.66 of this part, will be treated as an actionable violation of FIFRA section 6(a)(2).

(b) An actionable violation of FIFRA section 6(a)(2) means that EPA may recommend or seek to impose a civil and/or criminal penalty on the grounds that such a failure to submit information violates FIFRA section 6(a)(2).

(c) In the exercise of its enforcement discretion, EPA will not commence any civil penalty action or seek criminal prosecution of any registrant with regard to any failure to submit information under FIFRA section 6(a)(2) which is not treated as an actionable violation under this part. Sections 153.69 through 153.78 identify the types of information which must be submitted in order to avoid enforcement action by EPA.

(d) A registrant who violates FIFRA section 6(a)(2) commits an unlawful act under FIFRA section 12(a)(2)(N), 7 U.S.C. 136j(a)(2)(N), and may be subject to civil and/or criminal penalties under FIFRA section 14, 7 U.S.C. 136(1), including imprisonment up to 1 year and fines up to $25,000. The submission of false or misleading information is a violation of 18 U.S.C. 1001, and may result in the imposition of a fine up to $10,000 or imprisonment up to 5 years, or both.

(e) EPA will not automatically recommend or seek a civil or criminal penalty whenever it discovers an apparent violation of FIFRA section 6(a)(2) of a type which is considered actionable under this part. Decisions in such cases will be based on a careful evaluation of all pertinent information, including any explanation offered by the registrant.

§ 153.69 Completed toxicological studies.

(a) *Policy: Data that must be submitted.* The results of a completed study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which is otherwise reportable under § 153.66 must be submitted if:

(1) The substance tested had a kind of toxic or adverse effect, or an effect on an organ or tissue type, not observed in any study concerning the substance previously reported to EPA; or

(2) The substance tested had any toxic or adverse effect at a lower dosage, after a shorter exposure period, or after a shorter latency period, than in any study concerning that effect of the substance previously reported to EPA; or

(3) The substance tested had a more severe toxic or adverse effect, or a toxic or adverse effect which occurred at a higher incidence or frequency, than in any study concerning that effect of the substance previously reported to EPA; or

(4) The substance tested had a toxic or adverse effect in any species, strain, sex, or generation of test organism different from that in any study concerning that effect of the substance previously reported to EPA; or

(5) The substance tested had a toxic or adverse effect involving a route or medium of exposure not associated with such an effect in any study concerning the substance previously reported to EPA, if humans or other non-target organisms could conceivably be exposed to the substance by that route or medium; or

(6) The substance tested produced a toxic or adverse effect by means of a pharmacokinetic, metabolic, or biological mechanism different from any mechanism proposed for that effect in any study concerning the substance previously reported to EPA; or

(7) The substance tested had any toxic or adverse effect (even if corroborative of information already known to the Agency), if the substance is a pesticide, or an ingredient, impurity, metabolite, or degradation product of a pesticide which is the subject of a Registration Standard (reregistration)

proceeding, Special Review (or Rebuttable Presumption Against Registration (RPAR)) proceeding, suspension proceeding, or cancellation proceeding. For the purposes of this section a pesticide is subject to a proceeding when notice of commencement of such a proceeding has been published in the FEDERAL REGISTER and no notice of completion of the proceeding has been published. Upon publication of notice of commencement of any such proceeding each registrant must immediately submit all data in his possession required to be submitted by virtue of commencement of the proceeding and must submit any other such information within 15 working days from his receipt of it until announcement in the FEDERAL REGISTER of the completion of the proceeding.

(b) *Policy: Information found to be erroneous.* Information which is otherwise reportable under § 153.66 and paragraph (a) of this section need not be submitted if, within 15 working days of the date the registrant first has the apparently reportable information:

(1) The registrant discovers that any analysis, conclusion, or opinion which would have caused the information to be reportable was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors;

(2) Every author of each such analysis, conclusion, or opinion has acknowledged in writing that the analysis, conclusion, or opinion was improper because of the use of the erroneous data, and has corrected the original analysis, conclusion, or opinion accordingly; and

(3) After such corrections, the information is no longer required to be reported under any provision of this part.

(c) *Discussion of basis for policy.* (1) The result of any study in which exposure to a pesticidal substance is associated with a toxic or adverse effect is clearly pertinent to evaluation of risk and is thus legally reportable under section 6(a)(2). However, unless an item of toxicological information is the first of its category to be received by EPA, or unless it suggests that reliance on material previously submitted to EPA may have resulted in underestimation of risk, or was otherwise inaccurate, misleading, or incomplete, submission of such new information is not likely materially to affect the registration status of products containing the substance tested. EPA thus ordinarily will not treat failure to submit toxicological information which is essentially corroborative as an actionable violation of section 6(a)(2), but will insist on submission of any toxicological data which indicate that a pesticide may present different or greater hazards than previously identified.

(2) However, when a particular pesticide product is involved in a Special Review (RPAR) proceeding under part 154 of this chapter, or in suspension or cancellation proceedings under FIFRA section 6 (b) or (c), or where reregistration is underway, EPA's need for information is considerably greater. In such circumstances, the ultimate status of the pesticide depends on a comprehensive Agency reevaluation of the pesticide's risks and benefits, including an assessment of the reliability of previously submitted material and the extent to which it has been corroborated. Thus, if a particular substance is the subject of a reregistration, Special Review (RPAR), suspension, or cancellation proceeding, EPA will treat failure to submit any toxicologial information linking that substance with any toxic or adverse effect as an actionable violation of section 6(a)(2), regardless of whether or not such information merely confirms or corroborates prior data.

(3) By the time a study is ''completed,'' checking and validation of data should normally also be complete. The Agency will nonetheless allow the registrant a reasonable period, not to exceed 15 working days, to check for data errors which the registrant believes may have formed the basis for an opinion about what the data signify, and to seek a corresponding modification of the opinion. On the other hand, if it is not the data, but the expert analysis, conclusion, or opinion itself with which the registrant disagrees, the registrant's remedy is not to withhold the information from EPA, but to submit with the section 6(a)(2) report his own analysis of the information's significance.

[50 FR 38121, Sept. 20, 1985, as amended at 53 FR 15998, May 4, 1988]

§ 153.70 Incomplete toxicological studies.

(a) *Policy.* Information from an incomplete study of the toxicity to any organism of a registered pesticide product or any of its ingredients, impurities, metabolites, or degradation products which is otherwise reportable under § 153.66 must be submitted if the information is from:

(1) *Short-term studies.* A study utilizing a testing regimen lasting 90 calendar days or less, and:

(i) All testing has been completed;

(ii) A preliminary data analysis or gross pathological analysis has been conducted;

(iii) Final analysis has not been completed;

(iv) A reasonable period for completion of the final analysis not longer than 90 calendar days following completion of testing has elapsed;

(v) comparable information concerning the results of a completed study would be reportable under § 153.69; or

(2) *Long-term studies.* A study utilizing a testing regimen lasting more than 90 calendar days, and:

(i) All testing has been completed;

(ii) A preliminary data analysis or gross pathological analysis has been conducted;

(iii) Final analysis has not been completed;

(iv) A reasonable period for completion of final analysis (not longer than 1 year following completion of testing) has elapsed;

(v) Comparable information concerning the results of a completed study would be reportable under § 153.69; or

(3) *Serious adverse effects.* Any study in which testing or analysis of results is not yet complete but in which serious adverse effects have already been observed which may reasonably be attributed to exposure to the substances tested, because the effects observed in exposed organisms differ from effects observed in control organisms, are atypical in view of historical experience with the organism tested, or otherwise support a reasonable inference of causation and 15 working days have passed from the date the registrant first has the information.

(b) *Discussion of basis for policy.* (1) In developing a policy regarding which failures to submit otherwise reportable information from incomplete toxicological studies should be treated as actionable violations of section 6(a)(2), EPA has determined that it is not necessary at this time to require submission of preliminary or incomplete toxicological information, except in certain specific circumstances. The criteria selected are designed to accomplish two fundamental regulatory objectives. The first objective is to provide an incentive to registrants to complete analysis of toxicological data within a reasonable time, especially if a preliminary appraisal suggests that a pesticide may present different or greater hazards than those previously identified. The second objective is to ensure that any preliminary findings are reported to EPA as soon as there is a reasonable basis for concern, even though further testing or analysis may be necessary before the observed hazard can be defined or quantified.

(2) EPA does not currently believe that it would be useful to insist on submission of preliminary or inconclusive data on a routine basis. On the other hand, no registrant who fears immediate modifications of or additions to the study protocol or fears that submission of a completed study might jeopardize any of his registrations should be permitted indefinitely to defer or postpone completion of analysis of potentially significant data. Accordingly, the Agency has designated an appropriate period—up to 90 calendar days for short-term studies, up to 1 year for long-term studies—during which the registrant may engage in further analysis designed to complete the analysis of the data prior to submission.

(3) Certain types of preliminary experimental observations and findings are sufficiently serious that they should be reported to EPA within 15 working days. In general, the Agency will not treat failure to submit information concerning any incomplete study in which testing is still underway, or for which the prescribed period for analysis of results has not yet expired, as an actionable violation of section 6(a)(2) unless serious adverse effects have been observed which are sufficiently different from effects observed in control organisms or in prior experience with the test system that the registrant may reasonably assume that the adverse effects are associated with the pesticidal substance being tested. Even though preliminary information may not always be sufficiently complete or definitive to warrant immediate regulatory action, preliminary data may indicate a need for immediate modifications of or additions to the study protocol, provide a basis for requests for further information under FIFRA section 3(c)(2)(B), or convince EPA to conduct or sponsor additional research.

(c) *Examples of how policy will be applied.* (1) A registrant conducts the first study of the acute effects of ingestion of a certain pesticide on rabbits. A prior acute study of the same pesticide using mice found that exposed mice experienced increased mortality due to liver damage. The registrant notes increased mortality of unknown origin in the exposed rabbits. Following completion of the test regimen, the registrant may take a reasonable period, not exceeding an additional 90 calendar days, for investigation of the significance and cause of the increased mortality. After that period has elapsed, failure to submit information concerning the study to EPA will be treated as an actionable violation of section 6(a)(2), regardless of whether or not the analysis is yet complete, because information concerning a completed study in which toxic effects have been observed in a different species than previously reported would be reportable. Of course, the registrant will always be entitled to supplement any initial submission with the results of subsequent analysis.

(2) A registrant conducts a 2-year study of the effects of chronic exposure to a certain pesticide on rats. Nine months after the study commences, study personnel observe that a large percentage of the exposed rats have developed ocular opacity of the type associated with formation of cataracts. None of the control rats exhibits a comparable abnormality. Though the test is incomplete and the evidence that the pesticide is inducing cataracts is not yet definitive, the registrant may reasonably conclude that the ocular abnormalities are attributable to exposure to the pesticide, and the observed effects must be reported to EPA within 15 working days of the observation.

(3) A registrant conducts a 2-year study of the effects of chronic exposure to a certain pesticide

on mice. Six months after the study commences, incidence of death of exposed animals reaches a level such that significant doubt could arise that an inadequate number of animals would be at risk from the toxicological effects of the compound at the scheduled completion date. Though a substantial portion of the test regimen has not been completed, a reasonable inference arises that the unexpected effects are attributable to exposure to the pesticide, and the observed effects must be reported to EPA within 15 working days of the observation for the reasons specified in § 153.70(b)(3).

§ 153.71 Epidemiological studies.

(a) *Policy.* Information which concerns any epidemiological study (or portion thereof) involving correlation or association between exposure to a registered pesticide (or any of its ingredients, impurities, metabolites, or degradation products) and adverse effects in humans, and which is otherwise reportable under § 153.66, must be submitted regardless of whether or not the registrant considers any observed correlation or association to be significant.

(b) *Discussion of basis for policy.* Unlike most studies, which can be designed and controlled in advance, epidemiological studies are generally retrospective in character. As a consequence, it is often difficult to assess the impact of various uncontrolled variables on the magnitude of any observed correlation, and competent experts can reasonably disagree regarding the practical significance of epidemiological findings. On the other hand, epidemiological studies can be indispensable sources of information on the critical issue of the risks associated with human exposure. Thus, it is important that EPA be able to examine independently for relevance any epidemiological information concerning pesticide exposure, and the Agency will consider any failure to provide such information within 15 working days of receipt by the registrant to be an actionable violation of section 6(a)(2). Registrants may supplement any submission of epidemiological information with a statement describing any reservations they might have concerning the information's validity or significance.

§ 153.72 Efficacy studies.

(a) *Policy: information that must be submitted.* Information which concerns any study of the efficacy of a registered pesticide product and which is otherwise reportable under § 153.66 must be submitted if:

(1) The information demonstrates that the pesticide may not perform in accordance with any claim by the registrant regarding uses intended for control of organisms which may pose a risk to human health, including any of the uses identified in § 158.640 of this chapter; or

(2) The information concerns any deficiency or reduction in the claimed efficacy of any use of a registered pesticide, if such use is subject to a Registration Standard proceeding, Special Review (RPAR) proceeding, suspension proceeding, or cancellation proceeding as defined in § 153.69(a)(7).

(b) *Policy: information found to be erroneous.* Information which is otherwise reportable under § 153.66 and paragraph (a) of this section need not be submitted if, within 15 working days of the date the registrant first receives the apparently reportable information:

(1) The registrant discovers that any analysis, conclusion, or opinion which would have caused the information to be reportable was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors;

(2) Every author of each such analysis, conclusion, or opinion has acknowledged in writing that the analysis, conclusion, or opinion was improper because of the use of the erroneous data, and has corrected the original analysis, conclusion, or opinion accordingly; and

(3) After such corrections, the information is no longer required to be reported under any provision of this part.

(c) *Discussion of basis for policy.* (1) In most instances, EPA will not treat the failure to submit information concerning the efficacy of a registered pesticide product as an actionable violation of section 6(a)(2) unless such information indicates that the pesticide may not perform as claimed when used to control organisms which pose a potential threat to human health. The Agency has taken the position that the utility and efficacy of many pesticide products can best be verified by the mechanism of the marketplace.

(2) However, in instances where use of a particular pesticide appears to involve substantial hazards, EPA must evaluate the efficacy of the pesticide, in addition to the magnitude and value of its use and the feasibility of substitutes, before determining whether or not the risks associated with use of the pesticide are acceptable. Accordingly, whenever any use of a registered pesticide is the subject of a Registration Standard, Special Review (RPAR), suspension, or cancellation proceeding, as defined in § 153.69(a)(7), EPA will treat failure to submit within 15 working days any study which concerns any deficiency or reduction in the efficacy of the product for the use in question as an actionable violation of section 6(a)(2).

[50 FR 38121, Sept. 20, 1985, as amended at 53 FR 15998, May 4, 1988]

§ 153.73 Studies of dietary or environmental pesticide residues.

(a) *Policy.* Information which is otherwise reportable under § 153.66 from studies which show that levels of any active ingredients, metabolites, or degradates of pesticides may exceed established levels on food or feed, or which show any active ingredients, metabolites, or degradates of pesticides in ground water or elsewhere in the environment other than legally treated sites, must be submitted.

(b) *Policy: information found to be erroneous.* Information which is otherwise reportable under § 153.66 and paragraph (a) of this section need not be submitted if, within 15 working days of the date the registrant first receives the apparently reportable information:

(1) The registrant discovers that any analysis, conclusion, or opinion which would have caused the information to be reportable was predicated on data that were erroneously generated, recorded, or transmitted, or on computational errors;

(2) Every author of each such analysis, conclusion, or opinion has acknowledged in writing that the analysis, conclusion, or opinion was improper because of the use of the erroneous data, and has corrected the original analysis, conclusion, or opinion accordingly; and

(3) After such corrections, the information is no longer required to be reported under any provision of this part.

(c) *Discussion of basis for policy.* Such data are important to EPA efforts to learn about the existence and gauge the risk of pesticides in ground water and to verify or modify EPA's calculations of levels of exposure of the population to pesticides or their degradates or metabolites. Information on exposure is as important as data which indicate the toxicological effects of pesticidal chemicals to assessment of the potential risk associated with use of a chemical. If field monitoring studies or other information is available which might allow EPA better to protect public health or assess environmental fate by refining exposure calculations, it is imperative that EPA receive it. EPA establishes permissible levels of pesticides by setting tolerances and promulgating food additive regulations under the Federal Food, Drug, and Cosmetic Act (FFDCA).

(d) *Example.* The registrant knows that the original EPA decision to register his product for use as a soil insecticide in corn fields (the only registered use) was based on the belief that no detectable residues of a particular metabolite of the product would appear in corn planted in fields treated with the product or in ground or surface waters. In January the registrant learns of a study conducted by a university scientist showing that residues of the metabolite in question have appeared in corn grown in fields which were properly treated with the product. The information must be reported to EPA, unless during a reasonable period, not to exceed 15 working days for investigation or verification, the registrant learns of facts establishing it is untrue. One means of verification would be to conduct independent field trials during the coming growing season. However, waiting for the results of field trials would require a delay of at least 9 to 10 months in reporting. Given the potentially serious import of the information already available, a 9-month delay would be unreasonably long. Alternatively, the registrant could contact the scientist who conducted the study and review the raw data for errors. A registrant should be able to complete such a review within the 15 day timeframe for submission of information to EPA.

§ 153.74 Incident reports: general policy.

Registrants may receive information from incidents, rather than from studies, which is reportable under § 153.66. This information concerns specific incidents in which—

(a) Toxic or adverse effects have been attributed to exposure to the registrant's pesticide product;

(b) Residues in excess of established or expected levels have been reported; or

(c) It has been asserted that the registrant's pesticide product has failed to perform as claimed against designated target organisms. This information may come to the registrant's attention through a variety of sources, including but not limited to: Product liability claims and complaints; information obtained directly, or through field representatives, from dealers, growers and pesticide users; unpublicized reports from agricultural extension agents and Federal and State regulatory agencies; information received from the general public; information received from a poison control center; and information reported by plant managers and employees. Failure to submit information of this type will be considered an actionable violation of FIFRA section 6(a)(2) only to the extent set forth in §§ 153.75 through 153.78.

§ 153.75 Toxic or adverse effect incident reports.

(a) *Policy.* Information which is otherwise reportable under § 153.66 and which is described by paragraph (a) (1), (2), or (3) of this section must be submitted.

(1) *Human incidents.* The information concerns an incident in which:

(i) The registrant has been informed that some person suffered an adverse physiological or behavioral effect (other than local damage to or irritation of the skin or eye of the type commonly asso-

ciated with dermal or ocular exposure, when the label provides adequate notice of such a hazard);

(ii) The registrant has been informed that the affected person may have been exposed to the pesticide, or to one or more of its ingredients;

(iii) Either: (A) The registrant has verified that the person did suffer an adverse effect and was exposed to the pesticide; or

(B) The registrant has received sufficient information to enable investigation of whether or not the reported adverse effect and exposure occurred; 15 working days have elapsed; and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur; and

(iv) Either: (A) The registrant has concluded that the effect resulted or may have resulted from the exposure; or

(B) The registrant has been advised by any person described by § 153.66(b)(1) (i) through (iii) that the effect may have resulted from the exposure, and is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated.

(2) *Incidents involving other non-target organisms.* The information concerns an incident in which:

(i) The registrant has been informed of an adverse effect on non-target fish or wildlife, domestic animals, or plants;

(ii) The registrant had been informed that the affected fish, wildlife, domestic animals, or plants may have been exposed to the pesticide, or to one or more of its ingredients;

(iii) Either: (A) The registrant has verified that the reported adverse effect and exposure did occur; or

(B) The registrant has received sufficient information to enable investigation of whether or not the reported adverse effect and exposure occurred; 15 working days have elapsed, and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur; and

(iv) Either: (A) The registrant has concluded that the effect resulted or may have resulted from the exposure; or

(B) The registrant has been advised by any person described by § 153.66(b)(1) (i) through (iii) that the effect may have resulted from the exposure, and is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated.

(3) *Series of incidents.* The information concerns any series or pattern of individual incidents as to which:

(i) The registrant has been informed of the same kind of adverse effect on humans, non-target fish or wildlife, domestic animals, or plants; and

(ii) The registrant has been informed that the affected organisms may have been exposed to the same pesticide or to one or more of its ingredients; and

(iii) For each individual incident, either:

(A) The registrant has verified that the reported adverse effect and reported exposure did occur; or

(B) The registrant has received sufficient information to enable investigation of whether or not the reported adverse effect and exposure occurred, 15 working days have elapsed, and the registrant is not aware of facts which establish that the reported adverse effect or reported exposure did not occur; and

(iv) For each individual incident, the registrant is not aware of facts which conclusively establish that the reported adverse effect and reported exposure were unrelated; and

(v) The series or pattern of incidents would not be expected unless the reported adverse effects were caused by the reported exposures.

(b) *Discussion of basis for policy.* (1) Information concerning incidents in which toxic or adverse effects are attributed to pesticide exposure varies considerably in specificity and accuracy. Some reports received by registrants are so vague or implausible that they would be unlikely to provide a basis for administrative action. On the other hand, some incident reports may contain unique and valuable information on the hazards and environmental impacts associated with actual use and practice, information which cannot be readily derived from laboratory data alone. Thus, the Agency has endeavored to select sets of criteria which will give practical assistance to each registrant in identifying those types of incident information which are currently needed by EPA in order to discharge properly its statutory responsibilities. Each set of criteria contains the following elements: a report of a toxic or adverse effect; a report of pesticide exposure; an opportunity for investigation of the accuracy of the reports; and a basis for an inference that the toxic effect and the pesticide exposure were related.

(2) Demonstrably inaccurate incident information need not be submitted to EPA under section 6(a)(2). If a registrant can clearly demonstrate that a reported toxic effect or pesticide exposure did not occur, or that the effect and exposure were unrelated, the Agency will not treat any failure to report an alleged incident as an actionable violation of section 6(a)(2). However, failure to investigate the accuracy of any report or allegation which could be investigated will not be considered to excuse non-compliance with section 6(a)(2). By maintaining this policy, EPA does not intend to attempt to impose any sort of duty or obligation on the registrant to investigate incident reports, but rather to accord the registrant an opportunity to in-

vestigate incident information. In any event, the responsibility for determining the significance of any potentially useful incident information which has not been either verified or conclusively rebutted must ultimately reside from with EPA.

(3) Information concerning incidents in which humans exposed to a pesticide have experienced toxic or adverse effects is extremely useful in evaluating the occupational risks associated with pesticide use, deciding whether a method of applying the pesticide should be prohibited or that labeling should be changed. Receipt of incident information regarding adverse effects in humans is particularly important because of the ethical unacceptability of deliberate clinical exposure and the difficulties associated with predicting human toxicity on the basis of animal data. Thus, EPA may consider any failure to submit incident information concerning any toxic or adverse effect in humans (except for local damage or irritation of the skin or eye warned against on the label) which includes the basic elements previously identified and which is otherwise reportable under section 6(a)(2) to be an actionable violation of FIFRA, regardless of the circumstances which resulted in the pesticide exposure.

(4) In contrast, EPA will not treat failure to submit information on any single incident involving toxic or adverse effects on other non-target organisms as an actionable violation of section 6(a)(2) if the registrant can demonstrate that the pesticide was used improperly and that the label provides reasonable notice of the risk of adverse effects of the kind reported.

(5) Incident information concerning toxic or adverse effects has little current utility for regulatory purposes and need not be submitted to EPA under section 6(a)(2) unless the information is predicated on a conclusion, opinion, or reasonable inference that the reported effects were related to pesticide exposure. Failure to submit information regarding any single incident of this type will not be treated as a violation of section 6(a)(2) unless the registrant has concluded that the reported effect may have been caused by the reported pesticide exposure, or has been advised by any person described by § 153.66(b)(1)(i), (ii), or (iii) that a causal relationship may have existed.

(6) In contrast to paragraph (b)(5) of this section, if a registrant has been informed of a series or pattern of incidents in which the same kind of toxic or adverse effects has followed exposure to the same pesticide, a reasonable inference of a causal relationship may arise from the existence of the series or pattern itself, even in the absence of a specific conclusion or expert opinion to that effect. In such circumstances, any requirement that the registrant specifically concludes or is advised that a causal relationship exists is superfluous, and registrants will be held legally accountable under section 6(a)(2) for failure to submit information reporting any series or pattern of incidents involving the same kind of toxic or adverse effects from the same pesticidal substance. Moreover, even if a series or pattern consists of incidents which would otherwise not be reportable under this policy, because each incident involves predictable effects on non-target organisms resulting from improper use, EPA will likely treat failure to report such information in an aggregate form as an actionable violation of section 6(a)(2). EPA needs this type of incident information because the existence of widespread or routine misuse of pesticide products may be a basis for changes in labeling, additional restrictions on use, or other regulatory action.

(c) *Examples of how policy will be applied.* (1) A registrant receives a report from an unidentified source indicating that an agricultural employee experienced respiratory difficulties after working in a field where a pesticide manufactured by the registrant had recently been applied. The report is sufficiently detailed to enable investigation of its accuracy. A few days later, the registrant discusses the alleged incident with a toxicologist, who states that, in his opinion, the reported respiratory symptoms could have been caused by exposure to the registrant's pesticide. The registrant will be given a reasonable period of time after that discussion, not to exceed 15 working days, to investigate the incident. If the registrant discovers within that time facts which establish that the reported adverse effects or reported exposure did not occur, or which conclusively establish that the respiratory difficulties experienced by the exposed individual were caused exclusively by some factor other than pesticide exposure, the incident need not be reported. Otherwise, information concerning the incident must be submitted to EPA because the toxicologist is a qualified expert whose opinion is reportable under FIFRA section 6(a)(2).

(2) A registrant receives a report from an agricultural extension agent indicating that fish were killed in a creek adjacent to a field where a pesticide manufactured by the registrant had recently been applied. After investigation, not exceeding 15 working days, the registrant concludes that the reported fish kill probably resulted from exposure to the registrant's pesticide. However, the registrant also discovers facts which establish that the pesticide was improperly applied by an individual who disregarded a statement on the label expressly warning against use in circumstances where contamination of surface waters might result. Any single incident of this sort need not be reported under this section.

(3) The registrant has received reports of unusually high mortality in birds feeding in or near fields where the registrant's pesticide has been ap-

plied. Though some of these reports were not specific enough to enable investigation of their accuracy, the registrant has identified a series of three or more specific investigable incidents in which it appears that an unusual number of birds died following use of the registrant's pesticide. However, the registrant has not determined whether or not the pesticide was responsible for the observed increase in bird mortality, and no employee, consultant, or qualified expert has indicated that a causal relationship may exist. Nevertheless, the existence of the series of unexplained incidents is sufficient to support a reasonable inference of a causal relationship and excess residues, and failure to submit information concerning the incidents will be considered an actionable violation of section 6(a)(2).

§ 153.76 Failure of performance incident reports.

(a) *Policy.* Information which is otherwise reportable under § 153.66 and which is described by paragraph (a)(1) or (2) of this section must be submitted.

(1) *Immediate hazard to life.* The information concerns an incident in which:

(i) The registrant has been informed that a pesticide product did not perform as claimed against target organisms;

(ii) (A) The registrant has verified that the reported failure of performance did occur; or

(B) The registrant has received sufficient information to enable investigation of whether or not the reported failure of performance occurred, a period of 15 working days has elapsed, and the registrant is not aware of facts which establish that the reported failure of performance did not occur; and

(iii) The failure of the pesticide to perform as claimed involved any use against organisms which, unless controlled, may pose an immediate hazard to human life.

(2) *Health risk.* The information concerns a series or pattern of three or more individual incidents as to which:

(i) The registrant has been informed of the same type of failure to perform as claimed against target organisms;

(ii) For each individual incident, either:

(A) The registrant has verified that the reported failure of performance did occur; or

(B) The registrant has received sufficient information to enable investigation of whether or not the reported failure of performance occurred, a reasonable period of time, not exceeding 15 working days, for investigation has elapsed, and the registrant is not aware of facts which establish that the reported failure of performance did not occur; and

(iii) The failure of the pesticide to perform as claimed involved any use meant to control organisms which may pose a risk to human health, including any of the uses identified in § 158.640 of this chapter.

(b) *Discussion of basis for policy.* EPA will not treat any failure to submit, within 15 working days, information concerning incidents in which a pesticide did not perform as claimed against target organisms as an actionable violation of section 6(a)(2) unless the reported failure of performance involved organisms which pose a potential threat to human health. This policy reflects a judgment by EPA that the performance of pesticide products which are not used to protect public health can usually be adequately tested by the dictates of a competitive marketplace. Moreover, except in those instances where a reported failure of performance involved use against organisms which may pose an immediate hazard to human life, it is not likely that EPA would consider any single reported incident of failure of performance to be a proper basis for regulatory action. Therefore, the Agency will not treat any failure to submit, on time, incident information concerning failure of performance against organisms which may pose a risk to public health, but do not pose an immediate hazard to human life, as an actionable violation of section 6(a)(2) unless such information concerns a series or pattern of three or more comparable failures of performance. As in the case of incident information involving toxic or adverse effects, registrants will be afforded a reasonable opportunity to investigate any reported failure of performance before such information will be considered reportable.

[50 FR 38121, Sept. 20, 1985, as amended at 53 FR 15999, May 4, 1988]

§ 153.77 Dietary or environmental pesticide residue incident reports.

(a) *Policy.* Information which is otherwise reportable under § 153.66 from a report of one single incident which shows that levels of any active ingredient, metabolite, or degradate of a pesticide exceeds established levels on food or feed, or which show any active ingredient, metabolite, or degradate of a pesticide in ground water or elsewhere in the environment other than legally treated sites, must be submitted.

(b) *Discussion of basis for policy.* Such data are important to EPA efforts to learn about the existence of, and gauge the risk of, pesticides in ground water and to verify or to modify EPA's calculations of levels of exposure to pesticides or their degradates or metabolites. Information on exposure is as important as toxicological data to the assessment of the potential risk associated with

use of a chemical. EPA establishes permissible levels of pesticides by setting tolerances and promulgating food additive regulations under the Federal Food, Drug, and Cosmetic Act (FFDCA). Unlike the information required in § 153.73, EPA is requiring information regarding incidents to be submitted only if it shows, rather than may show, existence of excess levels of residues. Information from a single incident, or several reports of single incidents, may allow EPA to define assessments to how a pesticide is actually used in practice. It is to be noted that this section complements § 153.75 in that incidents involving improperly applied pesticides, while sometimes not reportable under § 153.75(b)(4), will be reportable under ths section if the specified excess residues result. Information showing excess residues resulting from performance studies conducted by, or on behalf of, a registrant is not considered information from an incident reportable under this section.

§ 153.78 Reporting of other information.

(a) *Policy.* Information of any kind other than those kinds of information described in §§ 153.69 through 153.77 must be submitted if:

(1) After a reasonable period of time for verification or investigation of the information has elapsed, not exceeding 15 working days, the registrant is not aware of facts which establish that the information is incorrect; and

(2) The registrant knows, or reasonably should know, that if the information should prove to be correct, EPA would regard the imformation alone or in conjunction with other information about the pesticide, as raising serious questions about the continued registerability of one or more uses of any of the registrant's pesticide products, or about the proper terms and conditions of registration of any such product.

(b) *Discussion of basis for policy.* (1) Sections 153.69 through 153.77 establish policies concerning the types of information which, insofar as EPA is aware, have been the subject of most of the inquiries made and concern expressed with regard to FIFRA section 6(a)(2). There are, however, many other categories of information which may be reportable under FIFRA section 6(a)(2) and § 153.66, including additional information concerning: The identity and amount of impurities and degradates of pesticide products in the product as sold; soil, plant, and animal metabolism; bioaccumulation by various life forms; levels of exposure to applicators, farm workers, bystanders, food consumers, and other persons above established levels, such as those established by the American Conference of Governmental Hygienists; drift of pesticides to non-target areas; and a variety of other information which might affect EPA decisions concerning the continued registerability of a product or the appropriate terms and conditions of registration.

(2) EPA has not attempted to establish with specificity, for each category of such additional information, which failures to report information EPA will or will not treat as actionable violations of FIFRA section 6(a)(2). This part may be modified in the future to announce a more specific section 6(a)(2) enforcement policy concerning some or all of these types of information.

(3) However, in order to provide some guidance to registrants, this part sets forth a general policy covering all information not described by §§ 153.69 through 153.77. It allows registrants a reasonable period, not exceeding 15 working days, to verify or investigate apparently reportable information. If, during this period, the registrant learns of facts showing that the information is incorrect, the information need not be submitted and failure to report will not be considered an actionable violation of section 6(a)(2).

(4) In addition, EPA will not treat a failure to report such additional information as an actionable violation of FIFRA section 6(a)(2) unless the registrant knew, or reasonably should have known, that EPA would regard the information as pertinent to the question of whether the product's registrations should be cancelled, suspended, or modified in some respect.

Subparts E—F [Reserved]

Subpart G—Determination of Active and Inert Ingredients

SOURCE: 53 FR 15989, May 4, 1988, unless otherwise noted.

§ 153.125 Criteria for determination of pesticidal activity.

(a) An ingredient will be considered an active ingredient if it is contained in a pesticide product and:

(1) The ingredient has the capability by itself, and when used as directed at the proposed use dilution, to function as a pesticide; or

(2) The ingredient has the ability to elicit or enhance a pesticidal effect in another compound whose pesticidal activity is substantially increased due to the interaction of the compounds. Compounds which function simply to enhance or prolong the activity of an active ingredient by physical action, such as stickers and other adjuvants, are not generally considered to be active ingredients.

(b) Normally the applicant will determine and state in his application whether an ingredient is ac-

tive or inert with respect to pesticidal activity. The Agency, as part of its review of an application for registration, or in conjunction with the Registration Standard or Special Review process, may require any ingredient, to be designated as an active ingredient if the Agency finds that it meets the criteria in paragraph (a) of this section. Conversely, the Agency may determine that any ingredient designated as active by an applicant is an inert ingredient if it fails to meet those criteria.

(c) If an ingredient is designated as an active ingredient, it must be identified in the label ingredients statement. If an ingredient is designated as an inert ingredient, it must be included as part of the total inert ingredients in the label ingredients statement.

(d) Designation of a substance as a pesticidally inert ingredient does not relieve the applicant or registrant of other requirements of FIFRA with respect to labeling of inert ingredients or submission of data, or from the requirements of the Federal Food, Drug, and Cosmetic Act with respect to tolerances or other clearance of ingredients.

[53 FR 15989, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.125 was amended by removing the parentetical phrase ''(including those listed in § 153.139)'' from paragraph (b), by removing paragraph (c) and redesignating paragraphs (d) and (e) as (c) and (d), effective August 18, 1995. For the convenience of the reader, the superseded text is set forth below.

§ 153.125 Criteria for determination of pesticidal activity.

* * * * *

(c) If an applicant or registrant submits data to the Agency which demonstrates to the Agency's satisfaction that an ingredient listed in § 153.139 is pesticidally active according to the criteria of this section, the ingredient may be deemed to be an active ingredient in that registrant's product.

* * * * *

§ 153.139 Substances determined to be pesticidally inert.

(a) *Antimicrobial products.* The Agency has concluded that the following ingredients normally have no independent pesticidal activity when included in antimicrobial products for the designated uses, and thus normally are properly classified as inert ingredients of such products, within the meaning of FIFRA sec. 2(m):

Substance	Uses
Acetone	Solvent.
Alkyl* amino betaine (*46 percent C_{12}, 24 percent C_{14}, 10 percent C_{16}, 6 percent C_{10}, 7 percent C_8, 5 percent C_{18}).	Corrosion inhibitor, surfactant.
Alkyl monoethanolamide	Emulsifier.
Aluminum chloride	Detergent.
Aluminum hyroxybenzenesulfate sulfonate	Emulsifier.
Aluminum powder	Filler.
Aluminum carbonate	Detergent.
Ammonium citrate	Sequestrant.
Ammonium lauryl sulfonate	Emulsifier.
Ammonium oleate	Detergent, emulsifier.
Ammonium oxalate	Detergent.
Amyl acetate	Diluent.
Borax	Detergent.
Butyl alcohol, tertiary	Solvent, odorant.
Carbon	Carrier, absorbent.
Castor oil	Emulsifier.
Citric acid	Sequestrant.
Diethanolamine dodecylbenzene sulfonate	Detergent.
Sodium oleate	Emulsifier.
Dimethyl phthalate	Perfume.
Disodium monoethanolamine phosphate	Emulsifier.
Dodecyl benzene sulfonic acid	Detergent.
Essential oils	Perfume.
Ethanol (ethyl alcohol)	Solvent, except in tinctures or where sole or major ingredient.
Ethanolamine	Emulsifier.
Ethanolamine dodecylbenzene sulfonate	Detergent.
Ethoxylated lanolin	Ointment base.
Ethylenediamine	Emulsifier.
Ethylenediaminetetraacetic acid (including all salts and derivatives).	Sequestrant.
Fumaric acid	Sequestrant.
Gluconic acid	Buffer.
Isooctyl phenoxy polyethoxy ethanol	Surfactant.
Isopropanol (isopropyl alcohol)	Solvent, except in tinctures, or where sole or major ingredient.
Isopropyl myristate	Solvent.
Juniper tar	Odorant.
Lauryl alcohol	Detergent, odorant.
Lauryl methacrylate	Emulsifier.
Limonene	Odorant, perfume.
Magnesium chloride	Builder.
Magnesium lauryl sulfate	Detergent.
Magnesium silicate	Odor absorbent.
Menthol	Perfume.
Methanol (methyl alcohol)	Solvent, except in tinctures, or where sole or major ingredient.
Methyl ethyl ketone	Solvent.
Methyl salicylate	Perfume, odorant.
Mineral oil, mineral seal oil, or white mineral oil.	Lubricant.
Monoethanolamides of the fatty acids of coconut oil.	Emulsifier.

Substance	Uses
Monosodium phosphate	Emulsifier, buffer.
Morpholine	Corrosion inhibitor.
Nonylphenoxypolyethoxyethanol	Surfactant.
Octylphenol	Nonionic surfactant.
Oil of citronella	Perfume, odorant.
Oil of eucalyptus	Perfume.
Oil of lemongrass	Perfume.
Oleic acid	Solvent.
Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, aliphatic hydrocarbons, paraffinic oil.	Lubricant, solvent.
Polyoxyethylene sorbitol, mixed ethyl ester of .	Emulsifier.
Polyvinylpyrrolidone	Emulsifier.
Potassium bisulfate	Builder.
Potassium carbonate	Detergent.
Potassium dodecylbenzenesulfonate	Anionic detergent.
Potassium laurate	Emulsifier.
Potassium myristate	Emulsifier.
Potassium *N*-(*s*-(nitroethyl)benzyl) ethylenediamine.	Emulsifier.
Potassium phosphate, tribasic	Sequestrant.
Potassium ricinoleate	Emulsifier.
Potassium toluene sulfonate	Detergent.
Potassium xylene sulfonate	Detergent.
Propanol (propyl alcohol)	Solvent, except in tinctures or where sole or major ingredient.
Soap	Detergent.
Sodium acetate	Buffer.
Sodium alkyl (100 percent C_9): benzene sulfonate.	Detergent.
Sodium bicarbonate	Detergent.
Sodium carbonate	Detergent.
Sodium chloride	Builder.
Sodium decylbenzene sulfonate	Detergent.
Sodium diacetate	Sequestrant.
Sodium dihydroxyethylglycine	Chelate, buffer.
Sodium diisopropylnaphthalene sulfonate	Detergent.
Sodium di(monoethanolamine) phosphate	Emulsifier.
Sodium dodecylbenzene sulfonate (may be active as a sanitizer in dishwashing formulations).	Detergent.
Sodium dodecyl diphenyl oxide sulfonate	Perfume.
Sodium glycolate	Sequestrant.
Sodium laurate	Detergent.
Sodium *N*-lauroylsarcosinate	Detergent.
Sodium lauryl sulfate	Detergent.
Sodium metasilicate	Detergent.
Sodium *N*-methyl-*N* oleyltaurate	Emulsifier.
Sodium mono and dimethyl naphthalene sulfonate.	Detergent.
Sodium oleate	Emulsifier.
Sodium phosphate	Emulsifier, buffer.
Sodium salt of turkey red oil	Emulsifier.
Sodium sesquicarbonate	Detergent.
Sodium silicate	Detergent.
Sodium sulfate	Detergent.
Sodium sulfonated oleic acid	Emulsifier.
Sodium thiosulfate	Builder.
Sodium toluene sulfonate	Detergent.
Sodium tripolyphosphate	Sequestrant.
Sodium xylene sulfonate	Detergent.
Tetrapotassium pyrophosphate	Sequestrant.
Tetrasodium pyrophosphate	Sequestrant.
Toluene sulfonic acid	Emulsifier.
1,1,1-Trichloroethane	Diluent.
Triethanolamine	Emulsifier.
Triethanolamine dodecylbenzene sulfonate	Detergent.
Triethanolamine laurate	Emulsifier.
Triethanolamine lauryl sulfate	Emulsifier.
Triisopropanolamine	Emulsifier.
Triisopropylamine	Emulsifier.
Trisodium phosphate	Detergent.
Turkey red oil	Emulsifier
Undecylenic acid	Perfume.
Xylene	Solvent.
Zirconium oxide	Dye.

(b) [Reserved]

(c) *Limitation.* This statement of policy does not bind decision makers in a formal adjudicatory proceeding under FIFRA sec. 3, 6, or 14. If this section becomes an issue in any such proceeding, the decision makers in that proceeding will make an independent judgment whether to adhere to it or not.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.139 was removed, effective August 18, 1995.

Subpart H—Coloration and Discoloration of Pesticides

SOURCE: 53 FR 15990, May 4, 1988, unless otherwise noted.

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if the Administrator determines that such requirements are feasible and necessary for the protection of health and the environment. This subpart describes those pesticide products which must be colored or discolored.

[60 FR 32096, June 19, 1995]

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.140 was revised, effective August 18, 1995. For the convenience of the reader, the superseded text is set forth below.

§ 153.140 General.

Section 25(c)(5) of the Act authorizes the Administrator to prescribe regulations requiring coloration or discoloration of any pesticide if he determines that such requirement is feasible and necessary for the protection of health and the environment. The Munsell Manual of Color, or its equivalent, shall be used as a color standard. References in §§ 153.145 and 153.150 to hues, values, chromas and neutral lightness refer to the Munsell Manual of Color.

§ 153.142 Coloring agent.

The coloring agent must produce a uniformly colored product not subject to change beyond the

minimum requirements specified in this subpart during ordinary conditions of distribution and storage and must not cause the product to be ineffective or result in adverse effects on non-target organisms when used as directed.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.142 was removed, effective August 18, 1995.

§ 153.145 Arsenicals and barium fluosilicate.

Standard lead arsenate, basic lead arsenate, calcium arsenate, magnesium arsenate, zinc arsenate, zinc arsenite, and barium fluosilicate shall be colored any hue, except the yellow-reds and yellows, having a value of not more than 8 and a chroma of not less than 4, or shall be discolored to a neutral lightness value not over 7.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.145 was removed, effective August 18, 1995.

§ 153.150 Sodium fluoride and sodium fluosilicate.

(a) Products containing sodium fluoride and sodium fluosilicate shall be colored blue or green having a value of not more than 2 and a chroma of not less than 4, or shall be discolored to a neutral lightness value not over 7.

(b) A product containing sodium fluoride shall be exempt from the requirements of this section if:

(1) It is intended and labeled for use as a fungicide solely in the manufacture or processing of rubber, glue, or leather goods.

(2) Coloration of the pesticide in accordance with these requirements will be likely to impart objectionable color characteristics to the finished goods;

(3) The pesticide will not be present in such finished goods in sufficient quantities to cause injury to any person; and

(4) The pesticide will not come into the hands of the public except after incorporation into such finished goods.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.150 was removed, effective August 18, 1995.

§ 153.155 Seed treatment products.

(a) Pesticide products intended for use in treating seeds must contain an EPA-approved dye to impart an unnatural color to the seed, unless appropriate tolerances or other clearances have been established under the Federal Food, Drug and Cosmetic Act for residues of the pesticide.

(b) The following products are exempt from the requirement of paragraph (a) of this section:

(1) Products intended and labeled for use solely by commercial seed treaters, provided that the label bears a statement requiring the user to add an EPA-approved dye with the pesticide during the seed treatment process.

(2) Products intended and labeled for use solely as at-planting or hopper box treatments.

(3) Products which are gaseous in form or are used as fumigants.

(c) EPA-approved dyes are those listed in § 180.1001 (c) and (d) of this chapter. Upon written request additional dyes will be considered for inclusion in this listing.

§ 153.158 Exceptions.

(a) Notwithstanding other provisions of this subpart, the Agency may exempt a product from the requirements of this subpart, or may permit other colors to be used for any particular purpose, if it determines that use of the prescribed color is not feasible for such purpose and is not necessary for the protection of health and the environment.

(b) Any pesticide product specified in this subpart which is intended solely for use by a textile manufacturer or commercial laundry, cleaner or dryer as a mothproofing agent, and which would not be suitable for such use if colored, and which will not come into the hands of the public except when incorporated into a fabric, is exempt from the requirements of this subpart.

EFFECTIVE DATE NOTE: At 60 FR 32096, June 19, 1995, § 153.158 was removed, effective August 18, 1995.

Subparts I-M—[Reserved]